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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,832	12/26/2001	David W. Morris	PP23698.0001/20366-027001	1729

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,832	MORRIS ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,28,30,32,33,35 and 39-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20, 28, 30, 32, 33, 35 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. The amendment filed 5/11/2007 is acknowledged. Claims 21-27, 29, 31, 34, and 36-38 were canceled. Clams 39-42 were added.

Claims 20, 28, 30, 32, 33, 35 and 39-42 are pending and examined on the merits.

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 112

2. The rejection of claim 35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claim.

3. The rejection of claims 21 and 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because of new matter is withdrawn in view of the amendment canceling claims 21 and 24.

4. The rejection of claims 20-24 under 35 U.S.C. 102(e) as being anticipated by Venter (US 6,812,339; issued Nov. 2, 2004; effective filing date Oct. 20, 2000) is withdrawn in view of the amendment to the claims.

5. The rejection of claims 20-26, 29, 30, and 34 under 35 U.S.C. 102(b) as being anticipated by Yamamoto (Yamamoto, M. et al. Leukemia, 13: 595-600, 1999) is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20, 28, 30, 32, 33, 35 and 39-42 remain/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of diagnosis of colon cancer comprising the differential detection of PPP3CC *protein* [emphasis added] levels, does not reasonably provide enablement for methods for diagnosing colon cancer, lymphoma, stomach cancer, prostate cancer, breast cancer or carcinoma, comprising either the differential detection of PPP3CC mRNA levels, where the PPP3CC mRNA is defined as a nucleotide sequence of SEQ ID NO: 1587 or a sequence at least 98% identical to SEQ IDNO: 1587. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is that the teachings of the specification do not enable the intended use of the claimed methods for the diagnosis of carcinoma (which encompasses any and all carcinomas), colon cancer, lymphoma, prostate cancer, stomach cancer or breast cancer because

the specification fails to provide evidence of differential expression of the nucleotide sequence of SEQ ID NO: 1587, or of differential expression of a nucleotide sequence that is at least 98% identical to SEQ ID NO: 1587.

Applicant's arguments have been carefully considered but fail to persuade. In the previous Office action, a post-filing date study indicating an association between calcineurin protein levels and stage of colon cancer was referenced (Lakshimikuttyama). Additionally it was noted that Kahara teaches that in leukemia, while calcineurin activity may be different between leukemic cells and non-leukemic cells, there was no indication that protein levels were different. Additionally it was noted that the specification fails to provide any supporting data for methods of diagnosing cancers such as colon cancer, lymphoma, prostate cancer, stomach cancer, breast cancer or carcinoma, where the supporting data demonstrates an association between an increase in calcineurin mRNA levels (SEQ ID NO: 1587) and colon cancer, or demonstrates any differential expression of calcineurin mRNA levels and any of the other cancers contemplated in the specification.

As a preliminary matter it appears that the original rejection was not understood, because applicant characterizes the examiner's rejection as containing the phrase "while being enabling for methods of diagnosis of colon cancer comprising the differential detection of PPP3CC levels", when the examiner indicated that what was enabled was the diagnosis of colon cancer comprising the differential detection of PPP3CC *protein* levels. Applicant argues that the Office is requiring data that is beyond the scope of the application and data that would be required by another government agency, such as the FDA. This argument is not persuasive because the Office is not requiring an extraordinary level of disclosure, but simply that applicant point to data

in the specification or in the post-filing date art that would support the conclusion that measuring, relative to a non-cancerous control, an increase in SEQ ID NO: 1587 or a sequence that is at least 98% identical to SEQ ID NO: 1587 would result in a method useful for the diagnosis of colon cancer. With respect to the other cancers there is no data for differential expression in either direction. Applicant argues that Tockman's requirements are not required by the statute. However, Tockman was cited to indicate the level of predictability in the field of cancer diagnosis using measurement of biological markers. Furthermore, applicant states that the present application sets forth the endpoint of the claimed methods as well as the expression levels indicative of cancer (two of three of Tockman's requirements). However, these teachings in the specification are prophetic. For the intended use of the claimed methods to be enabled there must be some teaching of an association between differential calcineurin mRNA expression and colon cancer, prostate cancer, lymphoma, breast cancer, or broadly, "carcinoma". In the absence of any data supporting the use of the methods of detection as a method for the diagnosis of carcinoma, colon cancer, lymphoma, prostate cancer, stomach cancer, or breast cancer, the specification presents merely an invitation to experiment.

7. Claims 20, 28, 30, 32, 33, and 39-42 remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the genus of mRNA expression products of PPP3CC that have greater than 98%

sequence identity to SEQ ID NO: 1587 and that are also diagnostic of cancer or diagnostic for a specific cancer. Therefore, the specification lacks adequate written description for the broadly claimed methods.

Applicant did not specifically address this rejection. Therefore the rejection is maintained for the reasons of record.

New Grounds of Rejection:

8. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is that the amendment introducing claim 42 introduces new matter into the specification as originally filed.

Claim 42 is dependent from either claim 20 or claim 39 and contains the limitation that the expression product at least 98% identical to SEQ ID NO: 1587 has the same expression profile as SEQ ID NO: 1587. Support for this limitation was not found in the passages cited by applicant. Nor was support found in a general review of the specification. The limitation that the expression product at least 98% identical to SEQ ID NO: 1587 has the same expression profile as SEQ ID NO: 1587 is not taught or contemplated in the specification, nor is it clear what is intended by this limitation. Therefore, one of skill in the art would not find that applicant was in possession of the invention as claimed at the time of filing.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
July 22, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER